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DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158 - 15 Liberty Avenue
Jamaica, New York 11433-1034

# WARNING LETTER

February 20, 2004

**CERTIFIED MAIL**
**RETURN RECEIPT REQUESTED**

Mrs. Kitty Kesler
President
Cardio Display Corp.
20 Vanderventer Avenue / Suite #101e
Port Washington, New York 11050

***Ref: NYK-2004-05***

Dear Mrs. Kesler:

During an inspection of your firm located in Port Washington, New York, conducted between the dates of January 16 – 27, 2004, our investigator determined that your firm manufactures a medical device under the brand name of "***CD-200 Cardiac Monitor***", a single channel, non-fade cardiac monitor intended for short, and long term monitoring of patient's ECG and heart rate via electrodes which are placed on the patient's skin surface. This is a device within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The device identified as the CD-200 Cardiac Monitor is adulterated within the meaning of section 501(h) of the Act, in that, the methods used in, or the facilities or controls used for the manufacturing, packaging, storage, or installation are not in conformance with good manufacturing practices, as specified in Title 21, ***Code of Federal Regulations (CFR)***, Part 820, Quality System Regulations for Medical Devices, and with the medical device reporting requirements of 21 CFR Part 803, as follows:

*1)* The Device History Record (DHR) does not include acceptance records that demonstrate the device is manufactured in accordance with the Device Master Record (DMR) as required by 21 CFR 820.184(d).

Specifically, the form CD20013/94, CD-200 Inspection and Testing Checklist, used to document the results of the final tests performed on the CD-200 Cardiac Monitors in accordance with the specifications in the DMR is not currently utilized. For example, the last documented CD-200 inspection and testing checklist was for the CD-200 S/N #940210, dated 03/30/94.

*2)* Your firm has failed to establish an adequate DMR for the CD-200 Cardiac Monitor as required by 21 CFR 820.181.

Although your firm does have schematics, drawings and diagrams for this device, the DMR *does not* include quality assurance procedures and specifications including acceptance criteria for device components, in-process testing, final testing, records prescribing the packaging and labeling specifications for this device and the location of any quality assurance procedures.

*3)* Written medical device reporting (MDR) procedures have not been developed, maintained and implemented as required by 21 CFR 803.17.

*4)* Complaint handling procedures for receiving, reviewing and evaluating complaints have not been established, defined, documented and implemented as required by 21 CFR 820.198(a).

*5)* Procedures for implementing corrective and preventative actions (CAPA) were not established, defined, documented and implemented as required by 21 CFR 820.100(a).

*6)* Procedures to control the design process of the device were not established, defined, documented and implemented as required by 21 CFR 820.30(a).

Specifically, the firm has not established, defined, documented and implemented procedures to control the design process for design changes and for any new devices designed.

*7)* Your firm has failed to establish, maintain, define and document the CD-200 Cardiac Monitor procedures for addressing the identification, documentation, evaluation, segregation, disposition and investigation of all non-conforming device products and components as required by 21 CFR 820.90(a).

*8)* Procedures for management review are not established, defined, documented and implemented as required by 21 CFR 820.20(c), to ensure that the firm's quality system is adequately maintained.

*9)* Procedures for conducting quality systems internal audits were not established, defined and documented as required by 21 CFR 820.22.

*10)* Procedures for finished devices and components acceptance activities were not established, defined, documented and implemented as required by 21 CFR 820.80(a).

*11)* Service reports do not include applicable test and/or inspection data as required by 21 CFR 820.200(d)(6).

*12)* There is no documentation of calibration equipment identification, calibration dates, the individual performing each calibration, and the next calibration date for inspection, measurement and test equipment as required by 21 CFR 820.72(b)(2).

Specifically, there was no such documentation maintained for the ECG simulator Model Valmedic and the digital multi-meter Model Textronic used in the final testing of the device.

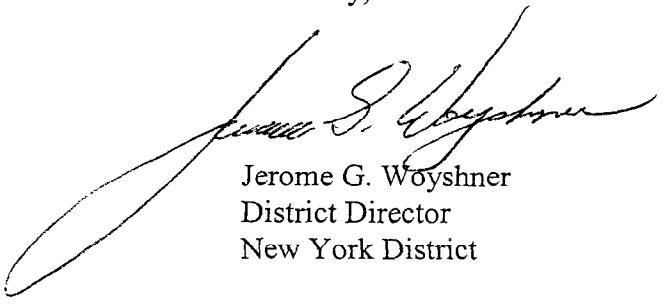
This letter is not intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure adherence with each requirement of the Act and the regulations. The specific violations noted in this letter and on the form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the Food & Drug Administration (FDA). If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to seizure, injunction and/or civil penalties. In addition, federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering award of contracts.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

Your reply should be sent to the attention of Arthur S. Williams, Jr., Compliance Officer, Food & Drug Administration, New York District Office, 158 - 15 Liberty Avenue, Jamaica, New York 11433 – 1034, (718)662-5568.

Sincerely,



Jerome G. Woyshner
District Director
New York District